SEP 2 2 2003

k032187
page 1 of 1

510(k) SUMMARY

Arthrex Titanium Opening Wedge Osteotomy System

NAME OF SPONSOR:

Arthrex, Inc.
2885 S. Horseshoe Drive
Naples, Florida 34104

510(K) CONTACT:

Sally Foust, RAC
Regulatory Affairs Specialist
Arthrex, Inc.
Telephone: (239) 643-5553 ext. 1251
FAX: (239) 430-3494
E-mail: sfoust@arthrex.com

TRADE NAME:

Arthrex Titanium Opening Wedge Osteotomy System

COMMON NAME:

Plates and Screws

DEVICE PRODUCT CODE, CFR No. & DEVICE CODE

HRS
21 CFR 888.3030

DEVICE DESCRIPTION AND INTENDED USE:

The Arthrex Titanium Opening Wedge Osteotomy System is comprised of plates and screws designed in various sizes to address patient needs. The plates are offered in an A/P sloped tibial plate, a non-sloped tibial plate, and a femoral plate design. The primary feature of the plates is a self-contained locking hole design. The screws are available in a cancellous and cortical design.

The Arthrex Titanium Opening Wedge Osteotomy System is used in conjunction with titanium bone screws to provide fixation following Proximal Tibial or Distal Femoral opening wedge osteotomies. The A/P sloped plates of the Arthrex Titanium Opening Wedge Osteotomy System are used following Proximal Tibial opening wedge osteotomies where tibial slope adjustments are required.

SUBSTANTIAL EQUIVALENCE SUMMARY

The Arthrex Titanium Opening Wedge Osteotomy System is substantially equivalent to the predicate devices where basic features and intended uses are the same. Any differences between the Arthrex Titanium Opening Wedge Osteotomy System and the predicate devices are considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, Arthrex, Inc. has determined that the Arthrex Titanium Opening Wedge Osteotomy System is substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 2 2003

Ms. Sally Foust, RAC
Regulatory Affairs Specialist
Arthrex, Inc.
2885 S. Horseshoe Drive
Naples, FL 34104

Re: K032187
Trade/Device Name: Arthrex Titanium Opening Wedge Osteotomy System
Regulation Numbers: 21 CFR 888.3030, 888.3040
Regulation Names: Single/multiple component metallic bone fixation appliances and accessories, Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Codes: HRS, HWC
Dated: July 16, 2003
Received: July 22, 2003

Dear Ms. Foust:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K032187

INDICATIONS FOR USE:

The Arthrex Titanium Opening Wedge Osteotomy System is used in conjunction with titanium bone screws to provide fixation following Proximal Tibial or Distal Femoral opening wedge osteotomies.

The A/P sloped plates of the Arthrex Titanium Opening Wedge Osteotomy System are used following Proximal Tibial opening wedge osteotomies where tibial slope adjustments are required.

Specifically for use in treatment of non-union, malunion, and fractures of proximal tibia and distal femur including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression, and fractures with associated shaft fractures.

It is intended to be used with adequate post-operative immobilization.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ____X____ OR Over-The-Counter Use

(Per 21 CFR 801.109)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032187